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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,006	06/19/2003	Andrew B. Arata	2003-0056	6057
41552	7590	08/12/2005	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/600,006	Applicant(s) ARATA, ANDREW B.	
	Examiner JOHN PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 26-35 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/28/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 8-10, 26-35 are pending in this application.

Applicant's election with traverse of the invention of Group I (claims 8-10 and 30) in the reply of 6/7/2005 is acknowledged.

The traversal is based on the argument that "a thorough search of the claims of either group will likely reveal art relevant to the examination of the claims of the other group." Applicant argues thereby that examination of both inventions should not place an undue burden on the Examiner. The Examiner cannot agree. The search of elected claims 10 and 30, for example, has nothing to do with electrolysis. Full examination of claims 8-9 requires searching in all search fields relevant to silver and citric acid per se. The search for the non-elected process claims requires searching in places where no pertinent art to the elected invention may be found. Technology such as spacing of the positive silver electrode in a certain manner and establishing a flow of silver ions to enable silver ions to react with the citric acid to form silver citrate would require review of a more general electrolysis technology that may not be relevant to citric acid. Review of general electrolysis technology is critically required for the non-elected invention, whereas the focus of the elected invention is in the composition content per se. Therefore, given the extensive challenge of reviewing the crowded art of silver antimicrobials, to search and examine an additional distinct invention would place an undue burden on the Examiner. For the previously stated reasons of distinctness, which is of record in the Office action of 12/8/2004, and the presently stated reasons of

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undue burden, the restriction requirement of record is still deemed to be proper. The restriction requirement is maintained, and is hereby made FINAL.

Accordingly, claims 26-29 and 31-35 are withdrawn from further consideration as being directed to non-elected subject matter, and claims 8-10 and 30 will presently be examined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al.

Srivastava et al. explicitly disclose a 0.5% solution of silver citrate in water (page 209, right column). Table I discloses antibacterial activity (page 211).

Claim Interpretation: Claim 8

Silver citrate "wherein the silver is electrolytically generated in a solution of citric acid and water" is noted in claim 8. For the purpose of examining the composition claim 8, in the absence of contrary evidence, silver generated electrolytically is treated indistinguishably from silver obtained non-electrolytically. Therefore, since Srivastava et al. disclose "an aqueous solution of silver citrate," the source of the silver fails to further distinguish applicant's claim 8.

Claim 8 also requires that the electrolytically generated silver has a concentration in excess of 0.05% by volume. "By volume" is interpreted to mean the volume that silver must take up in the aqueous solution. Claim 8 does not require that there is any leftover silver that is not complexed with the citric acid, save for equilibrium amounts. Hence, 0.05% by volume silver should be less than 0.05% by volume silver citrate. Srivastava's 0.5% silver citrate solution is 10 times more concentrated, although the specifics of the percentage are not explicitly stated. However, if the percentage is by volume, the feature is met. The only other likely alternative interpretation is % by weight since that is the standard percentage basis for antimicrobials. Since silver has a density higher than 10, it is reasonable to interpret 0.5 wt% silver citrate as exceeding 0.05 vol.% silver citrate. Therefore, under either interpretation of Srivastava's percentage basis, Srivastava's 0.5% silver citrate solution meets the concentration feature of applicant's claim.

The feature "extended shelf-life" is noted, but without more, such comparative language without objective comparison or specific shelf life cannot be given sufficient weight.

Claim Interpretation: Claim 9

Discussion of features in claim 9, which are also present in claim 8, are set forth above and incorporated herein. Claim 9 also requires that the silver is electrolytically generated in a solution of approximately 5-10% by volume of citric acid in water. This

feature fails to further distinguish over Srivastava et al. Nothing about this feature actually requires the presence of any citric acid in combination with silver citrate except for equilibrium amounts. What is claimed is the aqueous solution of silver citrate. The process language does not operate to connect the high amount of citric acid to what is actually being claimed.

Claim Interpretation: Claim 10

Silver citrate “in a solution of citric acid and water” is noted in claim 10. It is the Examiner’s position that Srivastava’s silver citrate in water is, like any other dissolved substance, in a state of equilibrium: $\text{AgCitrate} \leftrightarrow \text{Ag}^+ + \text{Citrate}^- \leftrightarrow \text{Ag}^+ + \text{Citric Acid}$. Therefore, without more, the “in a solution of citric acid and water” feature is necessarily met by Srivastava’s disclosure.

The feature, “wherein the concentration of silver citrate exceeds 0.05% by volume” is noted. “By volume” is interpreted to mean the volume that silver citrate must take up in the aqueous solution. Srivastava’s 0.5% solution is 10 times more concentrated, although the specifics of the percentage is not explicitly stated. However, if the percentage is by volume, the feature is literally anticipated. The only other likely alternative interpretation is % by weight since that is the standard percentage basis for antimicrobials. Since silver has a density higher than 10, it is reasonable to interpret 0.5 wt% silver citrate as exceeding 0.05 vol.% silver citrate.

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Therefore, under either interpretation of Srivastava's percentage basis, Srivastava's 0.5% silver citrate solution meets the concentration feature of applicant's claim.

The feature "extended shelf-life" is noted, but without more, such comparative language without objective comparison or specific shelf life cannot be given sufficient weight.

Claim Interpretation: Claim 30

The interpretation of claim 30 is analogous to that of claim 10, because the language of claim 30 is virtually identical to that of claim 10. The only difference in claim 30 is that it recites "aqueous solution" instead of "aqueous disinfectant" (claim 10). The "aqueous solution" feature is plainly met by the Srivastava's aqueous solution disclosure (page 209, right column, see the second sentence under "Material and methods"). Further, no matter how applicant characterizes the solution, Srivastava's antimicrobial 0.5% solution of silver citrate anticipates the solution of claim 30 for the same reasons as set forth above.

For these reasons, the claims are anticipated by Srivastava et al.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-9 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,197,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The patented claims disclose an aqueous disinfectant solution of silver citrate and citric acid, wherein silver ions are electrolytically generated in a solution of citric acid and water (claim 1). The citric acid final concentration is "greater than 1.0% citric acid by volume" (claim 4). The concentration of electrolytically generated silver citrate is equal to or greater than 5 ppm, based on the silver (claim 5).

The scope of the patented claims reads on very high and concentrated amounts of the electrolytically generated silver citrate. Since the same electrolytically generated silver citrate is claimed in the cited patent, the same extended shelf life must also be present. Therefore, one having ordinary skill in the art would have recognized the instant invention as an obvious variation of the invention claimed in the cited patent.

Claims 8-10 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8 of copending Application No. 10/434,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Copending claims are directed to an aqueous disinfectant comprising an aqueous solution of silver ion organic acid complex, wherein the silver is electrolytically generated in a solution of greater than 1% of the organic acid and water (claim 1). The organic acid includes citric acid (claim 5), and the acid amount is claimed as "approximately 2% or greater organic acid by volume" (claim 7). There is no specific percentage recitation for the silver in the copending claims.

While electrolytically generated silver "in excess of 0.05% by volume" or "0.05% to 0.1% by volume" is not explicitly disclosed in the copending claims, such amounts would have been obvious because of the proportionally large amount of citric acid to complex with silver. As for the specifics of 5-10% by volume of the citric acid in water, the Examiner's position is that "approximately 2% or greater organic acid by volume" in copending claim 7 is amply suggestive of such feature.

Therefore, one having ordinary skill in the art would have recognized the instant invention as an obvious variation of the invention claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 8, 10 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/846,221. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The copending claims are directed to a composition comprising an aqueous solution of silver citrate wherein the silver is electrolytically generated in a solution of citric acid and water. The only difference with the instant claims is the absence of disclosure as to silver in excess of 0.05% by volume or silver citrate in excess of 0.05% by volume. However, such amounts would have been obvious to one of ordinary skill in the art because higher amounts of silver and silver citrate would have been advantageous due to the known antimicrobial activity of silver. Therefore, one having ordinary skill in the art would have recognized the instant invention as an obvious variation of the invention claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 8, 10 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/060,013. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The copending claims are directed to a composition comprising an aqueous solution of silver citrate wherein the silver is electrolytically generated in a solution of citric acid and water. The only difference with the instant claims is the absence of disclosure as to silver in excess of 0.05% by volume or silver citrate in excess of 0.05% by volume. However, such amounts would have been obvious to one of ordinary skill in the art because higher amounts of silver and silver citrate would have been advantageous due to the known antimicrobial activity of silver. Therefore, one having ordinary skill in the art would have recognized the instant invention as an obvious variation of the invention claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

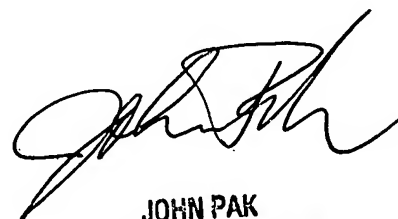
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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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